CLUNEAL NERVE STIMULATION AT 10 kHZ FOR THE TREATMENT OF CHRONIC NEUROPATHIC PAIN

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BACKGROUND

The superior cluneal nerves are formed from branches arising from the dorsal rami of the lower thoracic and upper lumbar roots. They pass through the paravertebral muscles and travel in a plane deep to the thoracolumbar fascia, piercing it just above the iliac crest. The medial branch crosses the iliac crest sometimes in a fibro-osseous tunnel approximately 8 cm from the midline, and the intermediate and lateral branches cross the iliac crest more laterally, although variably. The anatomy of the nerves in the region of the iliac crest is now well described (1,2) (Fig 1) and the more proximal course of the nerves less well known (3,4) and seems to involve the formation of a nerve plexus that eventually forms nerves that innervate the skin.

Traditionally, neuroablative efforts at relieving chronic low back pain within the distribution of the superior cluneal nerve has provided short-term benefits (10). Peripheral field stimulation has been used in the treatment of Failed Back Surgery Syndrome (FBSS), but reports have involved placing the leads just below the dermis in the area of the pain (11,12,13), rather than attempting to stimulate the nerves more proximally at the level of the fascia. Here, we present the use of paraesthesia-independent high frequency spinal cord stimulation (HF-SCS) at 10 kHz with the leads placed just superficial to the lumbar fascia over the superior cluneal nerve. HF-SCS has demonstrated long-term safety and efficacy in back and leg pain patients when placed within the epidural space (14). Illustrative cases will be presented, demonstrating the effectiveness of cluneal stimulation in the treatment of low back pain.

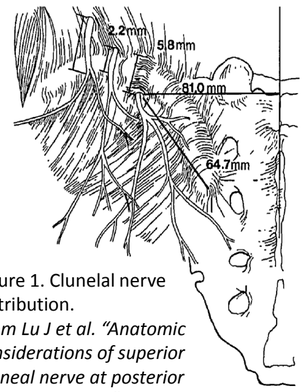

Figure 1. Clunelal nerve distribution.
From Lu J et al. "Anatomic considerations of superior Cluneal nerve at posterior iliac crest region." Clin Orthopedics and Rel Res. 347: 224-228 (1998)

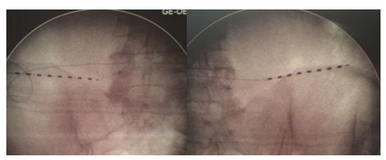

Figure 2. Leads placed subcutaneously, superficial to the lumbar fascia, bilaterally over the cluneal nerves.

METHODS

- Ten patients, four separate clinics (6 females)
- Intractable chronic low back pain localised within the innervation of the superior cluneal nerve.
- All patients reported using analgesics for pain management
- Patients selected for cluneal nerve stimulation, had either previously tried and failed epidurally placed traditional SCS systems, or had responded positively to an anaesthetic nerve block of the superior cluneal nerve.
- Following a history of failed conventional therapies and surgical intervention, under ultrasound guidance, patients underwent a 10 kHz stimulation trial using HF-SCS system, with up to two leads placed subcutaneously and laterally across the superior cluneal nerve (Figure 2).
- Stimulation parameters used included: 0-1.4 mA with 0.2 mA step size, 10 kHz and 30 µs.
- Two bipole multi area programming was used spanning over the cluneal nerve on each lead which was determined by paraesthesia testing of 60 Hz at 250 µs.

SUMMARY

Stimulating the superior cluneal nerve more proximally, and therefore potentially stimulating branches to the fascia as well as the skin, is proving to be a more efficacious approach to cluneal nerve stimulation. The use of HF-SCS at 10 kHz may prove to be a viable treatment option for pain localised over the cluneal nerve distribution in the lower back and unresponsive to spinal column stimulation.

HIGHLIGHTED CASE

- Male presented with failed back surgery syndrome, since 1998.
- Chronic neuropathic low back pain bilaterally above the belt line (Figure 2).
- Proceeded to a bilateral cluneal nerve stimulation implant following a successful trial period (Table 2).
- Patient reports clinically significant pain relief 6-months post implant (Figure 4)

Table 2. Cluneal nerve stimulation trial outcomes

Outcome Measure	Baseline	End of Trial
Numerical Pain Rating Scale	7	1
Medications	Targin 40/20 Targin 20/10	Targin 20/10
Brief Pain Inventory – Severity Score	6.3	0.8
Brief Pain Inventory – Interference Score	7	0.3
Pain Self Efficacy Questionnaire	11	56
The Lower Extremity Functional Scale	9	63
Oswestry Disability Index	74%	6%

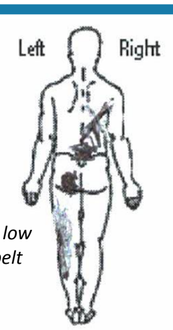

Figure 3. Pain distribution in the low back above the belt line.

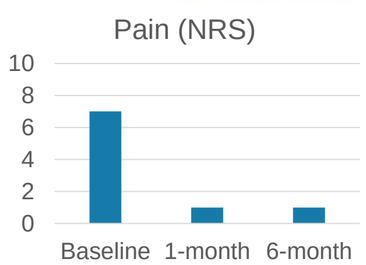

Figure 4. Despite failing conventional and surgical therapies, clinically significant pain relief was reported by the patient at 6-months post cluneal nerve stimulation implant

RESULTS

- Patients reported a reduction in baseline pain following implant (Table 1).
- Improvements in daily function and sleeping were reported, along with all but one patient reporting a reduction in their medication use.
- One patient (patient 4) passed away from an unrelated condition. No further complications were noted.

Table 1. Patient outcomes

Patient (time post implant)	Baseline Pain (NRS)	Post-Implant Pain (NRS)	Medication use	Sleep Quality	Functional changes
Patient 1 (44-months)	8	2	Decreased	Improved	Improved
Patient 2 (19-months)	9	0	Decreased	Improved	Improved
Patient 3 (6-months)	8	1	Decreased	Improved	Improved
Patient 4 (4-months)	10	0	Decreased	Improved	Improved
Patient 5 (5-months)	8	1	Decreased	Improved	Improved
Patient 6 (2-months)	7	1	Decreased	Improved	Improved
Patient 7 (3-month)	9	2	Decreased	Improved	Improved
Patient 8 (4-month)	9	4	Decreased	Improved	Improved
Patient 9 (1-month)	8	2	Decreased	Improved	Improved
Patient 10 (5-month)	7	1	Decreased	Improved	Improved

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